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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,708	10/13/2005	Gudmundur G. Haraldsson	01526.400600	8684

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FITZPATRICK CELLA HARPER & SCINTO
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EXAMINER

NAGUBANDI, LALITHA

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,708	Applicant(s) HARALDSSON ET AL.	
	Examiner Lalitha Nagubandi	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/13/2005</u> | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Status of the Claims

Claims 1-22 are pending. Claims 1-22 are considered in this office action.

Priority

This application is a 371 of PCT/NO03/00364 dated October 31st, 2003, which claims priority to Norway application no. 20025456 dated November 14th, 2002.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6, 7,12-19 ,21and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Haraldsson et al (Journal of the American Oil Chemists society, Vol. 74, No.11 (1997) pages 1419 to 1424.

For Claims 1-4, 6,7 see: page 1420, Para 2, lines 1-20

For Claims 12-16 See: see page 1420, Para 4 (see under Lipase-catalyzed ethanolysis), lines 1-8

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For Claims 17, 19, 21 and 22, See: page 1420, para 5, see under Results and discussion: lines 19- 20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1- 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haraldsson et al (Journal of the American Oil Chemists Society, Vol. 74, No. 11, pages 1419 - 1424 (1997) (Haraldsson 1) and in view of Haraldsson² et al (Journal of American Oil Chemists Society Vol. 75, No. 11 (1998) pages 1551 – 1556)(Haraldsson 2).

Applicants' claim a process for separating ethyl or methyl ester fraction enriched in EPA (eicosapentaenoic acid) and a free fatty acid fraction enriched in DHA (docohexaenoic acid) from a mixture by direct esterification of fish oil free fatty acids with ethanol or methanol using lipase, subjecting the said mixture to molecular distillation.

The process claims the lipase catalyst to be immobilized on a carrier. Further, applicants claim a process wherein the alkyl ester is hexyl ester.

Ascertainment of the difference between the Prior Art and Claims (MPEP §2141.02)

Haraldsson 1 et al teach the use of lipases as catalysts for separating the EPA and DHA in fish oil by transesterification, but does not teach the direct esterification of fish oil using alcohol. Haraldsson 2 et al teach direct esterification of fish oil using alcohol (see page 1553, right hand side column, and lines 5-8 (Esterification of fish oil). However, Haraldsson 2 does not explicitly teach the molecular distillation.

Both the references are silent about the hexyl esters, which are claimed, in the instant invention.

Finding of prima facie obviousness – rational and motivation (MPEP § 2142 - 2143)

It would be obvious to one of ordinary skill in the art at the time of instant invention, to alter the hydroxy components in order to obtain the desired esters as motivated from the teachings of Haraldsson.

Accordingly, one of ordinary skill in the art would be motivated to prepare the instant compounds by modifying the process parameters like changing the nature of the hydroxy solvent from ethanol to propanol to hexanol and subjecting to molecular distillation leading to the desired product as a cost effective process.

The examiner contends that the combination of references is proper and an ordinary artisan would have had a reasonable expectation of success at the time of the instant invention to arrive at the process and hence it is prima facie.

Claim Rejections - Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

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claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 and are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-20 and 22-24 of U.S. Patent No. 6,518,049 B1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over the reference claims.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-22 are generic to all that is recited in claims 11-20 and 22-24 of the U.S. Patent No. 6,518,049 B1. That is, the claims 12-20 and 22-24 of the US patent no. 6,518,049 B1 fall entirely within the scope of claims 1-22 of the instant application, specifically, claim 11 where lipase is immobilized on a carrier and claim 12 where lipase is *Rhizomucor meihei* and further in claim 16 and 24 where molecular distillation is performed. Thus the instant claims encompass the claims in the patent and are rejected under obviousness-type of double patenting.

Conclusion

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalitha Nagubandi whose telephone number is 571 272 7996. The examiner can normally be reached on 6.30am to 3.30pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lalitha Nagubandi
Patent Examiner
Technology Center 1600

April 30th, 2007.



Samuel A Barts Ph.D.

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